510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number: k041445

B. Purpose for Submission: New device

C. Analyte: Respiratory Syncytial Virus (RSV) antigens

D. Type of Test: Immunochromatographic test

E. Applicant: Meridian Bioscience, Inc.

F. Proprietary and Established Names: ImmunoCard STAT!® RSV

G. Regulatory Information:

1. Regulation section: 866.3480; RSV serological reagents
2. Classification: Class: I
3. Product Code: GQG; Antigens, CF, Respiratory Syncytial Virus
4. Panel: 83 Microbiology

H. Intended Use:

1. Intended use(s):

Immuno*Card* STAT!® RSV is a rapid, qualitative, lateral-flow immunoassay for the detection of Respiratory Syncytial Virus (RSV) antigens (fusion protein or internal protein) in human Nasal Wash, Nasopharyngeal Aspirate and Nasal and Nasopharyngeal Swab Samples. It is designed to test specimens from symptomatic neonatal and pediatric patients. It is recommended that all negative test results be confirmed by cell culture.

2. Indication(s) for use:

Immuno*Card* STAT! RSV is a rapid, qualitative, lateral-flow immunoassay for the detection of Respiratory Syncytial Virus (RSV) antigens (fusion protein or internal protein) in human nasal wash, nasopharyngeal aspirate and nasal and nasopharyngeal swab samples. It is designed to test specimens from symptomatic neonatal and pediatric patients. It is recommended that all negative test results be confirmed by cell culture.

3. Special condition for use statement(s): For prescription use

4. Special instrument Requirements: None

I. Device Description:

Immuno*Card* STAT! RSV uses monoclonal antibodies specific for the RSV fusion protein and an RSV internal protein as both the capture and detection antibodies. Nasal samples from wash, aspirate or swab are added to Sample Diluent Buffer using the transfer pipette provided with the kit. The diluted sample (approximately 1 in 2 dilution) is added to the sample port of the device. RSV fusion protein or internal protein antigen in the diluted sample binds to the corresponding monoclonal antibody-colloidal gold conjugate as the sample moves through the device. The antigen-antibody-colloidal gold complexes are captured by anti-RSV fusion protein and/or anti-RSV internal protein bound to the assay membrane at the test position of the device central window yielding a visible pink-red line.

J. Substantial Equivalence Information:

1. Predicate device name(s): Binax NOW® RSV
2. Predicate K number(s): k032166
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Method and type	Immunochromatography Rapid test Qualitative	Immunochromatography Rapid test Qualitative
Differences		
Item	**Device**	**Predicate**
Specimen Type	Nasal Wash, Nasopharyngeal Aspirate and Nasal Swab and Nasopharyngeal Swab	Nasal wash

K. Standard/Guidance Document Referenced (if applicable): Not applicable

L. Test Principle: Immunochromatography

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:* The reproducibility of Immuno*Card* STAT! RSV was determined using two panels of known negative (n = 2), positive (n = 5) and LOD (n = 1) samples that were coded and randomly sorted to prevent their identities. Two of the five positive samples were weakly reactive. Each reproducibility panel was tested on three consecutive days by three independent test sites. Test results with

one positive sample were reproducible at the rate of 94%. All other samples tested produced the expected results 100% of the time.

b. ***Linearity/assay reportable range:*** Not applicable

c. ***Traceability, Stability, Expected values (controls, calibrators, or method):*** Not applicable

d. ***Detection limit:*** The analytical sensitivity of this assay was established in tests with dilutions of three examples each of RSV strains A (VR-1540, VR-1302, VR-26) and B (VR-1401, VR-1400, VR-955). The lower limit of detection with these strains ranged from 10 to 10,000 virions/mL ($TCID_{50}$/mL).

e. ***Analytical specificity:*** The specificity of Immuno*Card* STAT! RSV was tested utilizing a number of bacterial, viral and yeast strains. Positive and negative respiratory specimens were spiked with $\geq$ 7.5 X 10^7/mL bacteria or yeast. Virus inoculations were performed at $\geq$ 1500 $TCID_{50}$ or $CEID_{50}$/mL. None of the microorganisms tested yielded a positive result in the RSV-negative sample or interfered with detection of the RSV-positive sample. Both the negative and positive respiratory samples were positive when spiked with RSV A strain VR-26.

f. Assay cut-off: Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Three independent laboratories tested Immuno*Card* STAT! RSV with samples from neonatal and pediatric patients that were characterized using cell culture. The specimens were tested either fresh or frozen.

Prospective samples:

		ICS RSV	
Fresh samples – Wash/Aspirate	Pos	Neg	Total
Tissue Culture Pos	7	2	9
Tissue Culture Neg	5	15	20
Total	12	17	29

Agreement 22/29 (75.9%)
Sensitivity 7/9 (77.8%)
Specificity 15/20 (75.0%)
Predictive value positive test 7/12 (58.3%)
Predictive value negative test 15/17 (88.2%)

		ICS RSV	
Fresh samples – Swab	Pos	Neg	Total
Tissue Culture Pos	15	4	19
Tissue Culture Neg	0	35	35
Total	15	39	54

Agreement 50/54 (92.6%)
Sensitivity 15/19 (78.9%)
Specificity 35/35 (100%)
Predictive value positive test 15/15 (100%)
Predictive value negative test 35/39 (89.7%)

Archived samples:

		ICS RSV	
Frozen samples– Wash/Aspirate	Pos	Neg	Total
Tissue Culture Pos	16	3	19
Tissue Culture Neg	0	0	0
Total	16	3	19

Agreement 16/19 (84.2%)
Sensitivity 16/19 (84.2%)
Specificity 0/0 (0%)
Predictive value positive test 16/16 (100%)
Predictive value negative test 0/3 (0%)

		ICS RSV	
Frozen samples – Swab	Pos	Neg	Total
Tissue Culture Pos	17	1	18
Tissue Culture Neg	3	51	54
Total	20	52	72

Agreement 68/72 (94.4%)
Sensitivity 17/18 (94.4%)
Specificity 51/54 (94.4%)
Predictive value positive test 17/20 (85.0%)
Predictive value negative test 51/52 (98.1%)

b. Matrix comparison: Not applicable

3. Clinical studies:

a. Clinical sensitivity: Not applicable

b. Clinical specificity: Not applicable

c. Other clinical supportive data (when a and b are not applicable): Not applicable

4. Clinical cut-off: Not applicable

5. Expected values/Reference range: Not applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.